K082927

BioResearch Associates, Inc.

510(k) Summary

FEB - 6 2009

BioResearch Associates, Inc.
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Official Correspondent: John Radke
15 September 2008

Trade Name: BioEMG III

Common Name: 8 channel electromyograph + 2 channel joint vibration amplifier

Classification Name: Diagnostic electromyograph (21 CFR 890.1375, Product Code KZM and NFQ

Equivalent Device: BioEMG II (K003176)

Product Description:

The BioEMG III is a multi-channel electromyographic amplifier which includes; a) eight (8) identical high-gain differential input amplifiers, b) eight (8) identical opto-coupler isolation units and c) eight (8) output buffer amplifiers. The overall amplification of the BioEMG III is calibrated to 5000X. The bandwidth filtering is set (fixed) from 30 Hz to 1000 Hz (± 3 dB). The common mode rejection ratio is ≥ 130 dB at the power line frequency (50/60 Hz). The BioEMG III includes an isolated power converter that converts non-isolated +5 vdc into isolated + 5 and - 5 vdc. It may be connected to a personal computer through an analog to digital converter. Only three (3) functions are provided by the BioEMG III; 1) amplification, 2) bandwidth limiting and 3) electrical isolation of the patient.

Analogous to the BioEMG II, the BioEMG III also incorporates two (2) additional inputs for recording vibrations from the left and right temporomandibular joints. They consist of: a) two (2) identical high-gain amplifiers and b) two (2) output buffer amplifiers. For these inputs no isolation is required because there is no electrical connection to the patient. The amplification is calibrated to 5000X and the bandwidth filtering is set from 30 Hz to 1000 Hz (± 3dB). These channels are also powered from an external +5 vdc non-isolated source, which is converted to +5 and - 5 vdc. The vibration signals may also be connected to a personal computer through an analog to digital converter. The two (2) functions performed by these "JVA" channels include: 1) amplification and 2) bandwidth limiting.

Intended Use for electromyography: (same as for BioEMG II - K003176)

1. To record electrical activity of muscles of the stomatognathic system, especially the temporalis, masseter and digastric

2. To clinically monitor up to eight different muscles as an aid in diagnosis and treatment evaluation by recording the electrical activity of the muscles of the stomatognathic system

3. To determine the degree of relaxation (intra-patient) of a single muscle / group of muscles at rest

4. To measure relative (intra-patient) levels of activity of several muscles during a functional act

Intended Use for joint vibration recording: (same as for BioEMG II - K003176)

1. To record and display sounds / vibrations from the temporomandibular joints

2. To aid the clinician in his analysis of a joint sound / vibration by allowing him/her to see the waveform in various standard plots

3. To aid the clinician in comparing a patient's current standard plots to previous recordings before, during and after treatment

4. To provide numerical values that can be used to quantify the physical characteristics of the sounds / vibrations, allowing intra-patient comparisons (only) by the clinician

Technological Characteristics:

The technological advantages of the BioEMG III (compared to the predicate device) include:

1) The use of surface-mount technology has reduced the BioEMG II 2-board design with interconnections to a 1-board design with higher theoretical reliability for the BioEMG III.

2) The elimination of the one mechanical switch (used to switch between EMG and JVA modes) on the PC board of the BioEMG II may reduce "wrong switch position operation."

3) A new "touchless" connector will allow activation of only the channels being used, reducing electrical interference from unused channels. As an indicator for the operator, a separate LED for each channel will light up whenever a lead is "plugged all the way in," activating that channel.

4) Due to the use of newer, low-power electronic components the BioEMG III will use less energy than the predicate device. This change should (theoretically) allow the BioEMG III to maintain its calibration longer than previously possible.

5) The functional characteristics of the BioEMG III are identical to those of the BioEMG II (K003176). See Exhibit G.

6) New features of the BioEMG III include; a) shielded lead-wires to minimized noise pickup from cell phone transmissions and b) a reference (isolated ground) continuity test circuit.

Non-clinical Test Data:

Utilizing a calibrated function generator and oscilloscope we have applied test signals to both instruments. In exhibit E we have supplied comparable graphic plots of the waveforms and the frequency response characteristics of both instruments. In the BioEMG III it is clear that we have retained the same levels of amplification, isolation and band-pass filtering as used in the BioEMG II predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Bio-Research Associates, Inc.
% Mr. John Radke
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Brown Deer, Wisconsin 53223

FEB - 6 2009

Re: K082927
Trade/Device Name: BioEMG III
Regulation Number: 21 CFR 890.1375
Regulation Name: Diagnostic electromyograph
Regulatory Class: Class II
Product Code: KZM
Dated: January 29, 2009
Received: January 29, 2009

Dear Mr. Radke:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

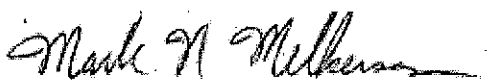
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082927

Device Name: BioEMG III

Indications for Use:

Indications for use: 8 channel EMG amplifier

1. To record electrical activity of muscles of the stomatognathic system, especially temporalis, masseter and digastric

2. To clinically monitor up to eight different muscles as an aid in the diagnosis and treatments evaluation by recording the electrical activity of muscles of the stomatognathic system

3. To determine the degree of relaxation (intra-patient) of a single muscle / group of muscles at rest

4. To measure relative (intra-patient) levels of activity of several muscles during a functional act

Indications for Use: 2 channel JVA amplifier

1. To record and display sounds / vibrations from the temporomandibular joints

2. To aid the clinician in his analysis of a joint sound/vibration by allowing him/her to see the waveform in various standard plots (together with K981563)

3. To aid the clinician in comparing a patient's current stand plots to previous recordings before, during and after treatment

4. To provide numerical values that can be used to quantify the physical characteristics of the sounds / vibrations, allowing intra-patient comparisons (only) by the clinician

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use Yes AND/OR Over-the-counter use ____
(Part 21 CFR 801 subpart D) (21 CFR 801 subpart D)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K082927